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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,146	12/10/2001	Jay Cunningham	3078/04	7806

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EXAMINER
SPIVACK, PHYLLIS G

ART UNIT	PAPER NUMBER
1614	10

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,146	Cunningham et al..	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *29 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5,7 and 9-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 5, 7, 9-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicants' Reply filed September 29, 2003, Paper No. 8, is acknowledged. Claims 2, 4, 6 and 8 are canceled. Claims 1, 3, 5, 7 and 9-13 remain under consideration.

It is noted the present Declaration does not refer to application S.N. 09/034,270 filed March 4, 1998.

A diligent, but unsuccessful, effort was made to locate all of the references cited on the Information Disclosure Statement filed September 29, 2003, Paper No. 9.

The disclosure is objected to for the following informality: Claim 9, a composition claim, depends from claim 1, a method of use claim.

Appropriate correction is required.

In the first Office Action claims 1-13 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,372,719.

Applicants argue the claims, as amended, are distinct from Patent 6,372,719.

Applicants' argument is not persuasive and the double patenting rejection of record is maintained. Overlapping subject matter remains.

Subsequent to the insertion into claim 1 of an active step involved in the method of use, the rejections of record of claims 1-4 under 35 U.S.C. 112, second paragraph, and 35 U.S.C. 101, are withdrawn.

Claims 1-13 were rejected in the last Office Action under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for treating or preventing any neoplasia disease.

Applicants argue the limitation "sensitive to the combination" delineates those neoplasms encompassed within the claims.

Applicants' arguments have been given careful consideration but are not found persuasive. The rejection of claims 1, 3, 5, 7 and 9-13 is maintained under 35 U.S.C. 112, first paragraph.

The claims are directed to the treatment or prevention of any neoplasia disease sensitive to the claimed combination of a compound of the formula of instant claims 1 and 5 and one of fourteen recited chemotherapeutic agents. The specification provides support for showing an additive effect following the administration of compound XII with cyclophosphamide or cisplatin to treat two distinct tumor cell lines.

Attention is directed to In re Wands, 8 USPQ2d 1400 where the court set forth factors to consider when assessing whether or not a disclosure would require undue experimentation. These factors are:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to treatment of any neoplasia disease sensitive to the claimed combination drug regimen and pharmaceutical compositions thereof.

The relative skill of those in the art is generally that of a Ph.D. or M.D.

Each particular neopastic disease has its own specific characteristics and etiology. The unpredictability observed with single agent therapy is compounded when a combination of agents is employed. The broad recitation "treating or preventing a neoplasia disease sensitive to the combination" is inclusive of many pathologies that presently have no established successful therapies.

It is clear the art to which the present invention relates is highly unpredictable and unreliable with respect to conclusions drawn from laboratory data extrapolated to clinical efficacy.

The breadth of the claims

The claims are very broad and inclusive of any neoplasia disease sensitive to the claimed combination.

The amount of direction or guidance provided and the presence or absence of working examples

The working examples are limited to a showing of an additive effect following the administration of compound XII with either cisplatin or cyclophosphamide in two distinct tumor cell lines.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to which particular chemotherapeutic agent in combination with which particular compound of the formula of claims 1 or 5 would be preferred for treatment or prevention of other neoplastic diseases, besides the two examples disclosed *supra*. The skilled artisan would expect the interaction of a particular combination of drugs in the treatment of a particular disease state to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis for each agent. The instant specification sets forth no such understanding nor any criteria for extrapolating beyond the combination of compound XII with either cyclophosphamide or cisplatin. Absent reasonable *a priori* expectations of success for using a particular chemotherapeutic combination to treat any particular neoplastic disease, one skilled in the oncology art would have to test extensively many combinations of agents to discover which particular disease responds to that particular combination. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

Claims 1-13 were rejected in the last Office Action under 35 U.S.C. 103 as being unpatentable over Rogers et al., U.S. Patent 6,013,651 and Remington's Pharmaceutical Sciences.

Applicants argue Rogers et al. is a co-owned patent that was filed on March 4, 1998 and assigned to G.D. Searle & Co. The inventors in the present case are under obligation to assign to G.D. Searle & Co.

Accordingly, the rejection of record under 35 U.S.C. 103 is withdrawn.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Phyllis G. Spivack at telephone number 703-308-4703.

Phyllis G. Spivack
Primary Examiner
Art Unit 1614

December 28, 2003

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER